UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA,

Plaintiff,

v.

RX DEPOT, INC. and RX OF CANADA, LLC, corporations, and CARL MOORE and DAVID PEOPLES, individuals,

Defendants.

NO. 03C V616 EA(M)

COMPLAINT FOR INJUNCTION

The United States of America, plaintiff, by and through its undersigned attorneys, respectfully represents to this Honorable Court as follows:

Introductory Allegations

1. This statutory injunction is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin Rx Depot, Inc. ("Rx Depot") and Rx of Canada, LLC ("Rx Canada"), corporations, and Carl Moore, President of Rx Depot, and David Peoples, Secretary of Rx Depot, individuals (hereinafter, collectively, "defendants") and all those in active concert and participation with any of them from violating:

a. 21 U.S.C. § 331(t), by importing, or causing the importation of, drugs in violation of 21 U.S.C. § 381(d)(1); and

b. 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for

introduction, into interstate commerce, drugs in violation of 21 U.S.C. § 355.

2. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c)).

4. The defendants cause the importation of prescription drugs from Canadian pharmacies, which clearly violates the law and poses significant risks to the public health. Drugs that are imported from foreign countries do not have the same assurance of safety and efficacy as drugs that are regulated by FDA. Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S.-manufacturer or authorized distributor, their quality is unpredictable. For instance, they may be contaminated, counterfeit, or contain erratic amounts of the active ingredient or different excipients. Also, the drugs may have been held under uncertain storage conditions, and therefore be outdated or subpotent.

5. In addition, the defendants expose their customers to potentially life-threatening problems by dispensing a greater quantity of drugs than is requested by the prescribing physician. Rx Depot advertises for, and causes the importation of, preset quantities of drugs and dispenses these preset quantities

regardless of how much of a drug the patient's U.S. physician prescribed and without directions to take the drug for only the number of days prescribed by the U.S. physician. U.S. patients can, therefore, take a drug for many days more than their physicians intend without supervision. This is particularly dangerous in instances in which the drug can have potentially life-threatening side effects with continued use.

Defendants

6. Defendant Rx Depot was incorporated under the laws of the State of Nevada on December 2, 2002, and does business at 4908 South Memorial Drive, Tulsa, Oklahoma, within the jurisdiction of this Court. Rx Depot also has stores located in: Grove, Oklahoma City, and Tulsa, Oklahoma; Lowell, Arkansas; La Mesa and Woodland Hills, California; Boulder, Colorado; Mountain Grove, Missouri; Lincoln, Nebraska; Carrollton and Paris, Texas; Port Charlotte and Fort Myers, Florida; Billings, Montana; and other locations in the United States. Rx Depot is engaged in the business of causing the shipment of U.S.-manufactured and unapproved, foreign-manufactured prescription drugs from Canadian pharmacies to U.S. citizens.

7. Defendant Rx Canada is a separate U.S. entity incorporated in Nevada. Rx Canada is owned by defendant Carl Moore's son, Joe-Max Moore. Rx Canada's website, www.rxofcanada.net, is substantially similar to www.rxdepot.com.

On the Rx Canada website, links to Rx Canada store locations are actually links to Rx Depot stores, including stores located in the Northern District of Oklahoma. Rx Canada is engaged in the business of causing the shipment of U.S.-manufactured and unapproved, foreign-manufactured prescription drugs from Canadian pharmacies to U.S. citizens and residents.

8. Defendant Carl Moore, an individual, is the President/Director of Rx Depot and a member of its Board of Directors. He has overall responsibility for, and authority over, all operations of the corporation, including the sales arrangements involving ordering, purchasing, and shipment of prescription drugs from Canada. He performs these activities at 4908 South Memorial Drive, Tulsa, Oklahoma, within the jurisdiction of this Court.

9. Defendant David Peoples, an individual, is the Secretary of Rx Depot. He is responsible for receiving and processing orders for Rx Depot. He performs these activities at 4908 South Memorial Drive, Tulsa, Oklahoma, within the jurisdiction of this Court.

How Defendants Conduct Business

10. The defendants have been and are now engaged at their locations in Oklahoma and other states in causing prescription drugs to be illegally imported into the United States from Canadian pharmacies. Each Rx Depot location has one or two

employees who accept prescriptions from U.S. customers. The customers also are asked to fill out a medical history form and other forms provided by Rx Depot. Rx Depot or the customer then faxes this information and the customer's credit card information to a cooperating pharmacy in Canada. A Canadian doctor rewrites the prescription, and the Canadian pharmacy fills the prescription, bills the U.S. customer's credit card, and mails the prescription drugs directly to the U.S. customer.

11. The defendants actively solicit other individuals to open affiliates and to further their business of causing the importation of prescription drugs from Canada by distributing promotional materials that describe their business practices and the potential profits to be made from opening a franchise. Defendants estimate that an affiliate would receive an average 9% commission on each sale of Canadian prescription drugs, about $24.75. The net commissions for an affiliate in the first year would be an estimated $141,570, according to the defendants.

The Violations

12. The defendants cause shipments of U.S.-manufactured drugs to be reimported into the United States. Reimportation of U.S.-manufactured drugs, even those approved for use in the United States, violates the Act, because only the manufacturer of a drug can reimport that drug into the United States. 21 U.S.C. § 381(d)(1).

13. The defendants also cause shipments of foreign-manufactured drugs to be introduced or delivered for introduction into interstate commerce. Some of these foreign-manufactured drugs are unapproved new drugs under 21 U.S.C. § 355.

14. In July - August 2003, an FDA agent made an undercover purchase of Sporanox from a Canadian pharmacy that was arranged by the defendants. Sporanox is an FDA-approved, prescription drug manufactured in Puerto Rico by Janssen Pharmaceutica, Inc., that is used to treat nail fungal infections. In late July 2003, an FDA investigator faxed an order for Sporanox to Rx Depot's Tulsa, Oklahoma, location. In early August 2003, FDA received the Sporanox order from Pharmacy North, Inc., in Winnipeg, Manitoba, Canada.

15. Defendants caused the Sporanox to be shipped back into the United States by a party other than the manufacturer and thereby violated 21 U.S.C. § 381(d)(1) and 21 U.S.C. § 331(t).

16. In early May 2003, FDA made another undercover purchase through Rx Depot. An FDA investigator visited an Rx Depot store located at 5801 N. May, Suite 101, Oklahoma City, Oklahoma. The investigator filled out the necessary order forms provided by Rx Depot and gave the owner a prescription for 60 pills, to be taken twice a day for 30 days, of the FDA-approved, prescription drug Serzone, which is used to treat depression.

17. In late May 2003, FDA received a package from Pharmacy North, Inc., in Winnipeg, Manitoba, Canada. The package contained 99 pills (and was labeled as containing 100) of a foreign-manufactured version of Serzone, known as APO-Nefazodone. The labeling did not direct the patient to take the drug for 30 days or for any other specified period of time.

18. APO-Nefazodone is a new drug within the meaning of the Act, 21 U.S.C. § 321(p), because it is not generally recognized by qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling.

19. Because APO-Nefazodone does not have in effect FDA approval of applications filed pursuant to 21 U.S.C. §§ 355(b) or (j), the drug is an unapproved new drug pursuant to 21 U.S.C. § 355(a). It does not have in effect a valid exemption from such approval requirements under 21 U.S.C. § 355(I).

20. The defendants violate 21 U.S.C. § 331(d) by causing the introduction or delivery for introduction into interstate commerce of drugs that violate 21 U.S.C. § 355.

21. The drugs purchased by FDA through undercover buys represent just two of the hundreds of drugs advertised on the defendants' websites.

Prior Warnings

22. The defendants have been warned about their violative conduct. On March 21, 2003, FDA issued a Warning Letter to the

Rx Depot site located at 200 S. Bloomington, Ste. E1, Lowell, Arkansas, with copies of the letter provided to defendants Moore and Peoples. The letter informed the defendants that they violate 21 U.S.C. § 381(d)(1), because they illegally cause prescription drugs manufactured in the United States to be reimported by persons other than the manufacturer of the drug. Further, the letter stated that the defendants violate 21 U.S.C. § 355 by causing unapproved new drugs to be imported into the United States.

23. On May 6, 2003, Rx Depot responded to FDA's Warning Letter. Rx Depot stated that all drugs it causes to be obtained from Canadian pharmacies are "manufactured in the United States." By so stating, Rx Depot not only admits violations of 21 U.S.C. § 381(d)(1), by causing the reimportation of U.S.-manufactured drugs, but it also made a false statement to FDA, because the evidence plainly demonstrates that the defendants also cause unapproved, foreign-manufactured drugs to be imported. The response also states that the drugs advertised on Rx Depot's website and obtained by Rx Depot's customers from Canadian pharmacies "'are not' FDA approved." By so stating, Rx Depot also admits that the importation of these unapproved drugs violates the Act. In its response, Rx Depot's stated justification for its importation of drugs is to make prescription drugs more affordable to American citizens. Rx

Depot did not indicate any intention to halt its illegal practices, but instead asked FDA to help it make lower-cost drugs available to consumers. By letter dated June 10, 2003, FDA informed the defendants that their response was inadequate.

24. During a May 12, 2003, inspection by FDA, defendant Moore told the FDA investigators that he intends to continue helping U.S. patients buy drugs from Canada until he is told by a court that it is illegal. The defendants' history of violations, and defendant Moore's comments, demonstrate the defendants' unwillingness to come into compliance with the Act. FDA has warned the defendants that their non-compliance would subject them to regulatory action. Notwithstanding this warning, the defendants have failed to comply with the Act, and their violations continue.

25. Defendants have repeatedly and publically stated that they intend to continue to violate the Act by causing the importation of prescription drugs from Canada until a Court tells them that doing so is illegal.

26. Plaintiff is informed and believes that, unless restrained by order of this Court, the defendants will continue to violate 21 U.S.C. §§ 331(t) and (d) in the manner set forth herein.

WHEREFORE, Plaintiff prays:

I. That defendants Rx Depot, Inc. and Rx of Canada, LLC, corporations, and Carl Moore and David Peoples, individuals, and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including but not limited to franchisees, affiliates, or "doing business as" entities), be preliminarily and perpetually restrained and enjoined from: directly or indirectly importing, or causing the importation of, any drug that violates 21 U.S.C. § 381(d)(1); and introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any drug that violates 21 U.S.C. § 355; and directly or indirectly receiving any commission associated with the refill of any prescription; and

II. That the Court award plaintiff costs and such other equitable relief, including but not limited to restitution to customers, as the Court deems just and proper.

Respectfully submitted,

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